PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Jaime Simon et al

Filed: Concurrently Herewith

Attorney Docket No.: 42801B

For: WATER-SOLUBLE POLYMERS FOR THE REDUCTION OF DIETARY PHOSPHATE OR OXALATE ABSORPTION

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DATE OF DEPOSIT: June 26, 2001

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

PRELIMINARY AMENDMENT

Prior to examination of the above-identified application, Applicants respectfully request amendment of the original Specification and Claims as follows:

IN THE SPECIFICATION

Please amend page 1 of the specification by inserting the following paragraph immediately after the title of the Invention:

-- Cross-Reference to Related Application

This application is a divisional of pending application serial number 09/091,998, filed June 23, 1998 (a 371 of PCT/US97/19322, filed October 22, 1997), which claims benefit from U.S. Provisional Application Serial No. 60/028,993 filed October 23, 1996, now abandoned. --

IN THE CLAIMS

Please cancel Claims 1-4, 6-15, and 17 in favor of prosecution in the parent application or another continuation application.

Please amend the Claims 18, 20, 22, 24-25, and 27-28 as follows:

18. (amended) A formulation for oral administration which comprises a water-soluble polyether glycol polymer which comprises: a structural backbone of carbon atoms and oxygen atoms where there are at least two consecutive carbon atoms present between each oxygen atom; a moiety on the backbone of the polymer or a functionalized derivative on the polymer, that is cationic at physiological pH and permits complexation with phosphate or oxalate; and an average molecular weight from about 5,000 to about 750,000 Daltons with a pharmaceutically-acceptable carrier.

20. (amended) A method for the reduction of phosphate or oxalate in vivo in an animal which comprises administering an effective amount of a formulation of Claim 18.

22. (amended) The method of Claim 21 wherein the effective amount for reduction of phosphate is from about 1 to about 15 grams per meal.

24. (amended) A use of a water-soluble polyether glycol polymer which comprises: a structural backbone of carbon atoms and oxygen atoms where there are at least two consecutive carbon atoms present between each oxygen atom; a moiety on the backbone of the polymer or a functionalized derivative on the polymer, that is cationic at physiological pH and permits complexation with phosphate or oxalate; and an average molecular weight from about 5,000 to about 750,000 Daltons as an agent for the reduction of phosphate or oxalate in vivo in an animal.

25. (amended) A process for preparing a water-soluble polyether glycol polymer which comprises: a structural backbone of carbon atoms and oxygen atoms where there are at least two consecutive carbon atoms present between each oxygen atom; a moiety on the backbone of the polymer or a functionalized derivative on the polymer, that is cationic at physiological pH and permits complexation with phosphate or oxalate; and an average molecular weight from about 5,000 to about 750,000 Daltons which process comprises reacting an epihalohydrin, in the presence of a Lewis acid of moderate strength, in a solvent that will not act as a chain terminator.

27. (amended) A process for preparing a water-soluble polyether glycol polymer which comprises: a structural backbone of carbon atoms and oxygen atoms where there are at least two consecutive carbon atoms present between each oxygen atom; a moiety on the backbone of the polymer or a functionalized derivative on the polymer, that is cationic at physiological pH and permits complexation with phosphate or oxalate; and an average molecular weight from about 5,000 to about 750,000 Daltons which process comprises reacting a 3,4-dichloro-1,2-butane oxirane, in the presence of a Lewis acid of moderate strength, in a solvent that will not act as a chain terminator.

28. (amended) The process for preparing a water-soluble polyether glycol polymer which comprises: a structural backbone of carbon atoms and oxygen atoms where there are at least two consecutive carbon atoms present between each oxygen atom; a moiety on the backbone of the polymer or a functionalized derivative on the polymer, that is cationic at physiological pH and permits complexation with phosphate or oxalate; and an average molecular weight from about 5,000 to about 750,000 Daltons wherein a catalyst is present selected from triethyloxionium hexafluorophosphate, fluoboric acid, triethyl aluminum, and 1,2-ethyl di(trifluoromethanesulfonate).

Remarks

The amendment to Specification indicates the status of related applications.

Claims 18-28 remain in the application. Claims 1-4, 6-15, and 17, which are already being prosecuted in the U.S. Application Serial No. 09/091,998, have been canceled. Claims 18, 24-25 and 27-28 have been amended. Claim 5 and 16 have already been canceled during the prosecution of U.S. Application Serial No. 09/091,998.

Claims 18, 24-25, and 27-28 have been amended to introduce the definition of a water-soluble polymer claimed in original Claim 1, now canceled.

Claims 20, 22 and 24 have been amended to correct the word "phosphonate" to read "phosphate". These amendments introduce no new matter since they involve correction of obvious typographic errors. Support for these amendments is found in the original specification and its claims.

Attached hereto is a marked-up version of the changes made to the specification and claims by this preliminary amendment. The attached page is captioned **"Version with markings to show changes made."**

Applicants respectfully request entry and consideration of the foregoing amendments.

Respectfully submitted,

Dragan J. Karadzic

Dragan J. Karadzic
Registration No. 28,024
Phone: (979) 238-2845

THE DOW CHEMICAL COMPANY
2301 N. Brazosport Blvd., B-1211
Freeport, Texas 77541-3257
June 26, 2001
DJK/alb

VERSION WITH MARKINGS TO SHOW CHANGES

In the specification

The following new paragraph has bee added at page 1 of the specification immediately after the title of the Invention:

"Cross-Reference to Related Application

This application is a divisional of pending application serial number 09/091,998, filed June 23, 1998 (a 371 of PCT/US97/19322, filed October 22, 1997), which claims benefit from U.S. Provisional Application Serial No. 60/028,993 filed October 23, 1996, now abandoned."

In the claims

Claims 1-17 have been canceled.

Claim 18 has been amended as follows:

18. (amended) A formulation for oral administration which comprises a water-soluble polyether glycol polymer which comprises: a structural backbone of carbon atoms and oxygen atoms where there are at least two consecutive carbon atoms present between each oxygen atom; a moiety on the backbone of the polymer or a functionalized derivative on the polymer, that is cationic at physiological pH and permits complexation with phosphate or oxalate; and an average molecular weight from about 5,000 to about 750,000 Daltons~~polymer of Claim 1~~ with a pharmaceutically-acceptable carrier.

Claim 20 has been amended as follows:

20. (amended) A method for the reduction of phosphate~~phosphonate~~ or oxalate in vivo in an animal which comprises administering an effective amount of a formulation of Claim 18.

Claim 22 has been amended as follows:

22. (amended) The method of Claim 21 wherein the effective amount for reduction of phosphate~~phosphonate~~ is from about 1 to about 15 grams per meal.

Claim 24 has been amended as follows:

24. (amended) A use of a water-soluble polyether glycol polymer which comprises: a structural backbone of carbon atoms and oxygen atoms where there are at least two consecutive carbon atoms present between each oxygen atom; a moiety on the backbone of the polymer or a functionalized derivative on the polymer, that is cationic at physiological pH and permits complexation with phosphate or oxalate; and an average molecular weight from about 5,000 to about 750,000 Daltons~~polymer of Claim 1~~ as an agent for the reduction of phosphate~~phosphonate~~ or oxalate in vivo in an animal.

Claim 25 has been amended as follows:

25. (amended) A process for preparing a water-soluble polyether glycol polymer which comprises: a structural backbone of carbon atoms and oxygen atoms where there are at least two consecutive carbon atoms present between each oxygen atom; a moiety on the backbone of the polymer or a functionalized derivative on the polymer, that is cationic at physiological pH and permits complexation with phosphate or oxalate; and an average molecular weight from about 5,000 to about 750,000 Daltons which process~~the polymer of Claim 1 which~~ comprises reacting an epihalohydrin, in the presence of a Lewis acid of moderate strength, in a solvent that will not act as a chain terminator.

Claim 27 has been amended as follows:

27. (amended) A process for preparing a water-soluble polyether glycol polymer which comprises: a structural backbone of carbon atoms and oxygen atoms where there are at least two consecutive carbon atoms present between each oxygen atom; a moiety on the backbone of the polymer or a functionalized derivative on the polymer, that is cationic at physiological pH and permits complexation with phosphate or oxalate; and an average molecular weight from about 5,000 to about 750,000 Daltons which process~~the polymer of Claim 1 which~~ comprises reacting a 3,4-dichloro-1,2-butane oxirane, in the presence of a Lewis acid of moderate strength, in a solvent that will not act as a chain terminator.

Claim 28 has been amended as follows:

28. (amended) The process for preparing a water-soluble polyether glycol polymer which comprises: a structural backbone of carbon atoms and oxygen atoms where there are at least two consecutive carbon atoms present between each oxygen atom; a moiety on the backbone of the polymer or a functionalized derivative on the polymer, that is cationic at physiological pH and permits complexation with phosphate or oxalate; and an average molecular weight from about 5,000 to about 750,000 Daltons which process~~polymer as defined in Claim 1~~ wherein a catalyst is present selected from triethyloxionium hexafluorophosphate, fluoboric acid, triethyl aluminum, and 1,2-ethyl di(trifluoromethanesulfonate).